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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Kevin C. Eggan and Rudolf Jaenisch

Application No.: 09/755,003 Group Art Unit: 1632

Filed: January 5, 2001 Examiner: S. Pappu

For: METHOD OF PRODUCING NON-HUMAN MAMMALS

CERTIFICATE OF MAILING

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REPLY TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Responsive to the Restriction Requirement dated December 4, 2001, the claims of Group II (Claims 7, 13-43 and 46-48), drawn to a method of producing a mutant mouse embryo and a mutant mouse, are elected for prosecution. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the non-elected invention(s). Applicants do not hereby abandon or waive any rights in the non-elected invention(s). The requirement is being traversed for the reasons set forth in detail below.

The Examiner states that restriction is proper in the subject application because (1) the inventions of Groups I, II and III are distinct; and (2) the inventions of each group have acquired a separate status in the art as shown by "their different classification" and "recognized divergent subject matter". The Examiner alleges that (1) the inventions of Groups I and II are distinct from each other because they "are drawn to methods of producing non-human mammals and mutant mice respectively" and thus "require materially different protocols"; (2) the inventions of Group I

and III are distinct from each other because they "are drawn to production of different types of animals (a non-human mammal vs. an XO female mouse) and thus require materially different methods"; and (3) the inventions of Groups II and III are distinct from each other because they "are drawn to producing different types of mice". Applicants respectfully traverse.

The two criteria for a proper requirement for restriction between patentably distinct inventions are that: (1) the invention must be independent or distinct as claimed; and (2) there must be a serious burden on the examiner if restriction is required (M.P.E.P. § 803). M.P.E.P. § 803 also provides that:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions (emphasis added).

Thus, Applicants request that Groups I, II and III be recombined. A search of the prior art for the inventions defined by Groups I, II and III is the same, given that the domestic and international classification for each invention is the same (e.g., U.S. Class 800). A search of the prior art for the methods and compositions defined by one group would also identify prior art that is applicable to the other groups. Furthermore, in light of the close relationship of the inventions of Groups I, II and III, a complete search of one invention would necessarily entail a search of the remaining invention(s). Thus, no excessive searching burden would be placed upon the Patent Office in examining Groups I, II and III together.

For the foregoing reasons, reconsideration and withdrawal of the restriction requirement regarding Groups I, II and III are respectfully requested.

Alternatively, Applicants request that Groups I and II and Claim 45 be recombined as the inventions of Groups I and II and Claim 45 are related to each other. Firstly, the methods relate to producing non-human mammals (e.g., mice, mutant non-human mammals, mutant mice, XO female mice) and non-human mammalian embryos (e.g., mice embryos, mutant non-human mammalian embryos, mutant mice embryos) by tetraploid blastocyst complementation using non-inbred pluripotent cells or cell lines and the compositions relate to the non-human mammals and non-human mammalian embryos produced by the methods. Thus, the inventions of Groups I and II and Claim 45 employ the same methods (i.e., tetraploid blastocyst complementation using non-inbred pluripotent cells or cell lines). In addition, the invention of Group I includes

embodiments which are also embraced by the invention of Group II and Claim 45. As such, restriction between Groups I and II and Claim 45 is improper.

Secondly, the Group I claims, the Group II claims and Claim 45 are related to each other as a genus and species. M.P.E.P. §§ 806.04 and 809.02. The claims of Group I entail the introduction of non-inbred pluripotent cells, which can be mutant or non-mutant cells, into tetraploid blastocysts of a non-human mammal. The claims of Group II entail the introduction of mutant non-inbred pluripotent cells into tetraploid blastocysts of a non-human mammal. Claim 45 entails the introduction of non-inbred XO F1 ES cells (non-inbred pluripotent cells), which can be mutant or non-mutant cells, into tetraploid blastocysts of a mouse. Accordingly, Group I is generic to and embraces Group II and Claim 45.

Thirdly, the Group I claims, the Group II claims and Claim 45 are further related to each other as a combination and subcombinations. Restriction between a combination and subcombination is generally proper where (1) the combination as claimed does not require the particulars of the subcombination for patentability and (2) the subcombination has utility by itself or in other combinations. M.P.E.P. § 806.05(c) requires that two-way distinctness needs to be satisfied where the inventions are related in this manner. The invention of Group II and Claim 45 requires the particulars of the invention of Group I for patentability. That is, the inventions defined by Group II and Claim 45 and by Group I require the introduction of non-inbred pluripotent cells into tetraploid blastocysts of a non-human mammal. The claims of the combination/subcombination also have the same utility, i.e., the claims in both groups are drawn to producing non-human mammals and non-human mammalian embryos. Thus, the two-way distinctness test cannot be satisfied and restriction between the claims of Groups I and II and Claim 45 is improper.

In addition, Applicants submit that the examination of Groups I and II and Claim 45 together would not place an undue burden upon the Patent Office. The search of the prior art for the inventions defined by Groups I and II and Claim 45 is the same, given that the domestic and international classification for each invention is the same (e.g., U.S. Class 800). A search of the prior art for the methods and compositions defined by one group would also identify prior art that is applicable to the other group. Furthermore, in light of the close relationship of the inventions

of Groups I and II and Claim 45, a complete search of one invention would necessarily entail a search of the remaining invention(s). Thus, no excessive searching burden would be placed upon the Patent Office in examining Groups I and II and Claim 45 together.

For the foregoing reasons, reconsideration and withdrawal of the restriction requirement regarding Groups I and II and Claim 45 are requested.

Respectfully submitted,

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